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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,592	02/12/2001	Beverly M. Emerson	1211.003US1	1304

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/08/2003 16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,592	EMERSON, BEVERLY M.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-88* is/are pending in the application.

4a) Of the above claim(s) *52,62,78 and 86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-43,48-51,53-61,63-69,74-77,79-85,87 and 88* is/are rejected.

7)☒ Claim(s) *44-47,70-73* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Final Rejection

Claims 38-88 are pending examination

Applicants' traversal in paper no. 15 filed on 7/14/03 is acknowledged and considered.

Election/Restrictions

This application contains claims 52, 62, 78, and 86 drawn to a nonelected invention with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claims 42 and 68 are objected to because of the following informalities: the word "motif" is misspelled. Appropriate correction is required.

Claims 57 and 83 remain objected to because of the following informalities: a bracket after the word "LCR". Suggest replacing the bracket with a closed parenthesis ")". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-43, 48-51, 53-61, 63-69, 74-77, 79-85, 87-88 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 38-43, 48-51, 53-61, 63-69, 74-77, 79-85, 87-88 as best understood, are readable on a genus of subunits of chromatin remodeling complex associated with a domain of a nucleic acid regulatory protein, wherein the genus of one or more subunits of chromatin remodeling complex associated with a domain of a nucleic acid regulatory protein is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates using a genus of one or more subunits of chromatin remodeling complex associated with a domain of a nucleic acid regulatory protein. The as-filed specification provides sufficient description of a chromatin remodeling complexes selected from SWI/SNF, RSC, NURF, CHRAC, ACF, NURD, and RSF. The specification and the art of record provide sufficient description of SWI/SNF subunits associated with a domain of nucleic acid regulatory proteins (e.g. transcription factor). However, the specification does not provide sufficient description of a representative number of subunits of other chromatin remodeling complexes that associated with a domain of a nucleic acid regulatory protein. The specification states that, "there are seven chromatin-remodeling complexes and several properties indicate that

these complexes are functionally and mechanistically distinct" (page 3). In addition, the art of record states, "the process by which SWI/SNF and other chromatin remodeling complexes activate specific subsets of genes is poorly understood" (IDS, Kadam et al., Genes & Development, 14:2441-2451, 2000). The specification does not describe the domains of a representative number of chromatin remodeling complexes. The art of record and the specification do not disclose a known correlation and function between SWI/SNF and a genus of chromatin remodeling complex. It is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of one or more subunits of chromatin remodeling complex associated with a domain of a nucleic acid regulatory protein as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of one or more subunits of a chromatin remodeling complex that must exhibit the disclosed biological functions as contemplated by the claims.

It is not sufficient to support the present claimed invention directed to a genus of one or more subunits of chromatin remodeling complex associated with a domain of a nucleic acid regulatory protein. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of one or more subunits of a chromatin remodeling complexes that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is

not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of the claimed one or more subunits of a chromatin remodeling complexes that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant's arguments filed 7/14/03 have been fully considered but they are not persuasive.

The argument that, "one skilled person could have envisioned the claimed invention given that numerous chromatin remodeling complexes had been described in the art at the time the filing and are described in the specification (See pages 6-7), is not found persuasive. It is acknowledged the as-filed specification provides sufficient description of a chromatin remodeling complexes selected from SWI/SNF, RSC, NURF, CHRAC, ACF, NURD, and RSF, however, the argument is not found persuasive because the specification does not provide sufficient description of a representative number of subunits of chromatin remodeling complexes

associated with a domain of a nucleic acid regulatory protein. The specification does not disclose a known correlation and function between subunits of a SWI/SNF and subunits from a genus of chromatin remodeling complex. The art of record teaches that a variation exist between subunits of SWI/SNF depending on the species (Aalfs et al., TIBS, Vol. 25, pages 548-555, 2000). There are no specific structural identifying features discloses for one or more subunits for a genus of chromatin remodeling complexes. There is no description in the specification to teach one skilled in the art what constitutes a subunit associated with a domain of a nucleic acid regulatory protein in a genus of chromatin remodeling complex.

Claims 38-43, 48-51, 53-61, 63-69, 74-77, 79-85, 87-88 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to identify a test compound that modulates the chromatin remodeling complex (SWI/SNF), does not reasonably provide enablement for a method to identify a test compound that modulates one or more subunits of chromatin remodeling complex associated with a domain of a nucleic acid regulatory protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possession of a genus of one or more subunits of a chromatin remodeling complexes associated with a domain of a nucleic acid regulatory protein), particularly in view of the reasons set forth above, one skilled in the art would not have known how to use and make the

claimed invention so that it would operate as intended, e.g. used to identify a test compound that modulates chromatin remodeling of a specific DNA sequence within chromatin.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The invention is directed to methods of identifying test compounds for modulating chromatin remodeling of a specific DNA sequence within chromatin.

The art of record states, "the process by which SWI/SNF and other chromatin remodeling complexes activate specific subsets of genes is poorly understood" (IDS, Kadam et al).

In addition, the art of record displays that, "little is known about the manner in which remodeling complexes disrupt nucleosomes" and "mechanism to explain gene regulation have become increasingly sophisticated over the past few years" and "challenges will be how to decipher how remodeling and modification machinery modulate the nucleosomal structure of heterochromatin, centromeres, and telomeres as well as regulate distinct nuclear processes" (IDS, Armstrong et al. Curr. Opin. Genet. Dev. 8:165-172, 1998).

The as-filed specification teaches:

> Mammalian SWI/SNF complexes exist in broad classes depending on whether they contain the subunit BRG1 or BRM as their DNA-dependent ATPase. Zinc finger DNA-binding domain specificity is only achieved with BRG1-containting SWI/SNF complexes. BRM complexes presumably interact with another class of transcription factors. This is very advantageous because it further demonstrates the degree of specificity that chromatin-remodeling complexes employ to regulate distinct subsets of genes (page 10).

Thus, making and using a genus of chromatin remodeling complexes associated within a domain of a nucleic acid regulatory protein is considered highly unpredictable.

The specification teaches *in vitro* experiments that demonstrate how mammalian chromatin remodeling complexes (SWI/SNF) regulate transcription (Example 1, pages 18-19). Furthermore, the specification teaches that SWI/SNF selectively functions with several zinc finger DNA-binding proteins to remodel chromatin and activate transcription in vitro (pages 19-21). Example 2, a pharmaceutical screening protocol is contemplated the claimed methods (pages 26-29). Example 3, the specification teaches that activation of repressed genes by facilitated protein binding through targeted chromatin remodeling by zinc finger protein motifs and SWI/SNF (pages 29-30). Example 4, the specification uses an assay to display that either β-globin gene with SWI/SNF + EKLF or the gamma-globin gene are differently activated with a novel protein complex and this assay can be used as a high-throughput drug screening assay (page 30). Example 5, the specification teaches an in vitro assay has been developed that reproduced p-53 dependent activation of the p21 cell cycle inhibitor gene and this assay can be used for high-throughput screening of drugs that enhance or interfere with protein interaction (pages 31-32).

The specification provides sufficient guidance for one skilled in the art to make and use one or subunit from SWI/SNF associated with domains from different regulatory proteins, but does not provide sufficient guidance or factual evidence for one skilled in the at to practice the full scope of the claimed embodiment. The specification contemplates using subunits associated with a domain of a nucleic acid regulatory protein from a genus of chromatin remodeling complexes and list several chromatin complexes. However, the specification only discloses domains of nucleic acid regulatory proteins that associate with subunits from SWI/SNF (pages 8-9). The state of the art at the time the application was filed displays that there are numerous

distinct nucleic acid regulatory proteins and SWI/SNF has been found to associate with diverse regulators of gene activation and cell proliferation (Kadam, pages 2441-2451). Furthermore, several chromatin-remodeling complexes are considered newly discovered (ACF, CHRAC) and the association between subunits of these complexes and nucleic acid regulatory proteins is not certain (Armstrong, pages 166-167). Armstrong also states that, "new chromatin remodeling complex, FACT found in humans appears to function quite distinctly from other chromatin remodeling complexes as it does not facilitate transcription initiation or require ATP hydrolysis" (page 167). In view of the In Re Wands Factors, the as-filed specification does not provide sufficient guidance for what subunits of other chromatin remodeling complexes are associated with a domain of any nucleic acid regulatory protein.

In addition, in view of the breadth of the genus of chromatin remodeling complexes from different organism (yeast, Drosophila, human, etc.) that have not been disclosed by the specification and are absent from the art of record (See Armstrong pages 166-167), the specification does not provide a representative number from each genus of chromatin remodeling complex for one skilled in the art to practice the genus of chromatin remodeling complexes recited in the claims.

As a result, it is not apparent how one skilled in the art determines, without undue experimentation, how to reasonably correlate from the chromatin remodeling complex, SWI/SNF to the genus of chromatin remodeling complex (e.g. Armstrong pages 166, teaches that, "in a transcriptional assay NURF cannot be replaced by either yeast SWI/SNF or CHRAC"), how is it apparent as to how one skilled in the art, without any undue experimentation, practices the full breadth of any method as contemplated by the claims, particularly given the unpredictability of

making and using a genus of chromatin remodeling complexes associated within a domain of a nucleic acid regulatory protein and/or the doubts expressed in the art of record.

In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made lack sufficient guidance and/or evidence to reasonably enable the full breadth of the claimed invention. Given that there is no representative number of subunits of a chromatin remodeling complex and a domain within a nucleic acid regulatory protein. In addition, since the disclosure does not provide sufficient guidance for what, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicant's disclosure and the unpredictability of using a genus of chromatin remodeling complexes associated with a domain of a nucleic acid regulatory protein.

Applicant's arguments filed 7/14/03 have been fully considered but they are not persuasive.

The argument that, "given the guidance provided by the specification, only standard and well-known techniques not requiring undue experimentation, would have been required to practice the invention methods (page 9)," is not found persuasive. The argument is not found persuasive because in view of the In Re Wands Factors, the as-filed specification does not provide sufficient and/or factual guidance for one skilled in the art to practice the full scope of the claimed method. The specification does not provide sufficient guidance or factual evidence that only standard and well-known techniques would be required to practice the invention methods. The breadth of the claims recites using a genus of chromatin remodeling complexes and the specification only teaches subunits of SWI/SNF. The specification does not teach subunits of other chromatin remodeling complexes. The art of record for making and using one

or more subunits associated with a domain of a nucleic acid regulatory protein of a genus of chromatin remodeling complex in the claimed method is considered unpredictable.

The argument that, "the Federal Circuit clearly stated that routine experimentation does not constitute undue experimentation (see pages 9 and 10)," is not found persuasive. The argument is not found persuasive because the specification and art of record do no teach that making and using the claimed method would only require routine experimentation. The assertion provided by the applicants is not supported by any factual evidence and/or guidance in the specification that the claimed method only required routine experimentation.

The argument that, "While exemplified with regard to the SWI/SNF chromatin remodeling complex, the skilled person would have been able to apply the teaching to test, for example, other known remodeling complexes given that all chromatin remodeling complexes modulate nucleosomal structure through association with a nucleic acid regulatory protein" is not found persuasive. The argument is not found persuasive because while it is acknowledged that other chromatin remodeling complexes are known, the one or more subunits associated with a domain of a nucleic acid regulatory protein are not known. Other than the subunits for the SWI/SNF, the as-filed specification does not teach a representative number of one or more subunits associated with a domain of a nucleic acid regulatory protein of a genus of chromatin remodeling complex for one skilled in the art to practice the full scope of the claimed method. The art of record teaches that a variation exist between subunits of SWI/SNF depending on the species (Aalfs et al., TIBS, Vol. 25, pages 548-555, 2000). The art of record further teaches that, "the remodeling fields greatest weakness at present is a failure to make meaningful connections between in vivo and in vitro data, partially because many of the mechanisms observed both in

vivo and in vitro are poorly defined." (Aalfs, *supra*). Furthermore, several chromatin-remodeling complexes are considered newly discovered (ACF, CHRAC) and the association between subunits of these complexes and nucleic acid regulatory proteins is not certain (Armstrong, pages 166-167). The specification does not teach how to reasonably extrapolate from the subunits of SWI/SNF to one or more subunits associated with a domain of a nucleic acid regulatory protein of a genus of chromatin remodeling complex.

In response to the attorney's assertion that, "all chromatin remodeling complexes modulate nucleosomal structure through association with a nucleic acid regulatory protein." The assertion is not found persuasive because MPEP § 716.01(c) states:

> The arguments of counsel cannot take the place of evidence in the record. In re Schulze,346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

The art of record teaches that, "ISWI-based complex to be involved in the activation of promoters where nucleosomes are either absent or re-positioned to make a promoter more accessible." (Aalfs, *supra*). Furthermore, the specification does not teach what subunit(s) of a genus of chromatin remodeling complexes are involved with a nucleic acid regulatory protein.

The argument that, "The existence of inoperative embodiments does not defeat the enablement of claims where the specification adequately teaches one skill in the art how to

choose operative from inoperative embodiments" (pages 11-12) is not found persuasive. The argument is not found persuasive because the specification does not teach one skilled in the art how determine operative/inoperative embodiments. The applicants do not provide where the specification teaches how to determine inoperative embodiments from operative embodiments. Furthermore, with respect to the assertion that, "the specification adequately teaches one skill in the art how to choose operative from inoperative embodiments."

The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

> It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.
> In re Vaeck, 947 F.2d 48, 496 & n.23. 30 USPQ2d 1438, 1445 &n23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel. 984 F.2d.1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [Footnote omitted].

On this record, it is apparent that the specification provides no more than a plan or invitation in view of the art of record exemplifying the unpredictability of using one or more subunits associated with a domain of a nucleic acid regulatory protein of a genus of chromatin remodeling complex in the claimed method, for those skilled in the art to experiment with the claimed method as intended by the as-filed specification at the time the invention was made.

See also Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997)

> ("Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the public to understand and carry out the invention.")

In view of the art of record and the lack of guidance provided by the specification; the specification does not provide reasonable detail for what subunit(s) are required for different chromatin remodeling complex, and it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from guidance in the specification to the full breadth of the claimed invention. Therefore, the as-filed specification is not enabled for the full scope of the claimed invention.

Conclusion

Claims 44-47 and 70-73 are objected to as being dependent upon a rejected base claim (claims 38 and 63), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER